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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,856	03/05/2001	Yat Sun Or	ENP019	5605

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EXAMINER
LIU, SAMUEL W

ART UNIT	PAPER NUMBER
1653	5

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/800,856	OR ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-1 are pending and the following is applicable to the pending claims.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4 and 8, drawn to a cyclosporin peptide and a process of making , are classified in class 530, subclass 317, class 514, subclass 2 and 11.

II. Claims 5-7, drawn to a method of making the cyclosporin and derivatives via an organic synthesis, are classified in class 530, subclass 333 and 335.

III. Claims 9-11, drawn to a method of treating inflammatory disease by Administering pharmaceutical composition comprising cyclosporin, are classified in class 514, subclass 2 and 11, class 424, subclass class 278.1, and class 604, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Invention II and Invention I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, as opposed to the claimed process (Claims 5-7), Leitner, E. et al. teach recombinant synthesis of cyclosporin peptides in which the peptides are synthesized by cyclosporin synthetase (see US Pat. No. 5827706). In addition, Billich A. et al. (*J. Biol. Chem.* (1987) 267, 17258-17259) teach that unusual amino acid residue, e.g. L-novavaline, methyl-Leucine and other

modified residues con be incorporated into cyclosporin structure by an enzymatic synthesis in combination of chemically synthesized residues (see especially page 17259).

Invention I and Invention III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the synthesized cyclosporin derivatives can used as an inhibitor for permeability transition pore in mitochondria during apoptosis.

Inventions II and III are related as different and/or distinct methods, a method of making the cyclosporin and derivatives via synthesis, and a method of treating inflammatory disease using pharmaceutical composition comprising the cyclosporin. These two methods differ with respect to method steps, end-products, targets, ingredients; therefore, each method is patentably distinct.

Additional Election Under 35 USC 121

Regardless of the elected group, applicant is required under 35 US 121 (1) to elect a single disclosed peptide to which claims are restricted; and (2) to list all claims readable thereon including those subsequently added.

If Group I is elected, applicant is required under 35 US 121 (1) to elect a Y chemical group from Claims 1 and 3; a cyclosporin derivative from Claim 4, since these organic groups are chemically different and none of them can be substituted one for other, and each cyclosporin derivative are both structurally and functionally different which are required different synthetic

procedure and modification and has different pharmacological efficacy toward therapeutic application.

If group III is elected, applicant is required under 35 US 121 (1) to elect a disease state from claim 11 because each disease state required different pathological mechanism, route of administering of pharmaceutical composition, treatment procedure and outcome of treatment. For example, mechanism for asthma, a disorder caused by airways in lungs are inflamed and swollen; muscles surrounding your airways, irritated by inflammation, tighten and constrict spontaneously; and membranes in airway linings secrete excess mucus, which results in narrowed airways and obstructed airflow that typically lead to coughing, wheezing and shortness of breath is different from the mechanism causing allergic rhinitis, an immune disorder involving the antibody immunoglobulin E, or IgE. Therefore, method of treatment for both diseases are different.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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September 25, 2002